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EXAMINER	
BALASUBRAMANIAN, VENKATARAMAN	
ART UNIT	PAPER NUMBER
1624	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	03/22/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/660,115	AXON ET AL.	
	Examiner	Art Unit	
	Venkataraman Balasubramanian	1624	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11 October 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1 and 4-23* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1 and 4-23* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

A pre-appeal conference was held and it was suggested that examiner should revise the 112 first paragraph rejection providing current references and also revise 103 rejections explaining the factual basis for these rejections. Accordingly, the following revised rejections are applied to currently pending claims. In addition a new ground of rejection is applied to pending claims.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1 and 4-23 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

1. Recitation of " or the hetero forms of any of the foregoing" in R^2, R^3, R^4 choices claim 1 and in Ar choice of claim 4 renders these claims and their dependent claims 5-23 indefinite as it is not clear what is intended. The structural make-up of the various R^2, R^3, R^4 choices to be derived from the said hetero forms remain unknown and the scope of the claim is not clearly defined.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 20 is rejected under U.S.C. 112, first paragraph, because the specification while being enabling for treating fibrosis of liver, does not reasonably provide

enablement for treating any or all fibroproliferative disorders or any or all cancers due to or unwanted activity of generically embraced in the claim language. The specification does not enable any physician skilled in the art of medicine, to use the invention commensurate in scope with these claims.

The instant compounds are disclosed to have TGFβ inhibitory activity and it is recited that the instant compounds are therefore useful in treating any or all fibroproliferative disorders or any or all cancers for which applicants provide no competent evidence.

It appears that the applicants are asserting that the embraced compounds because of their mode action as TGF-β inhibitor that would be useful for all sorts of any fibroproliferative disorders and cancers. However, the applicants have not provided any competent evidence that the instantly disclosed tests are highly predictive for all the uses disclosed and embraced by the claim language for the intended host.

The scope of the claims involves millions and millions of compounds of claim 1 as well as the thousand of diseases embraced by the terms fibroproliferative disease, and cancer operating through TGF receptors.

Proliferative disease would include benign tumors, malignant tumors, polyps, lumps, lesions, other pre-cancerous conditions, psoriasis, leukemia, the hyper proliferation of the gastric epithelium caused by the Helicobacter pylori infection of ulcers.

Cancer is just an umbrella term. Tumors vary from those so benign that they are never treated to those so virulent that all present therapy is useless. There are

hundreds of such diseases, which have fundamentally different mechanisms and different underlying causes. Thus, the scope of claims is extremely broad.

No compound has ever been found to treat cancers of all types generally. Since this assertion is contrary to what is known in medicine, proof must be provided that this revolutionary assertion has merits. The existence of such a "compound" is contrary to our present understanding of oncology. Cecil Textbook of Medicine states, "each specific type has unique biologic and clinical features that must be appreciated for proper diagnosis, treatment and study" (see the enclosed article, page 1004). Different types of cancers affect different organs and have different methods of growth and harm to the body. Thus, it is beyond the skill of oncologists today to get an agent to be effective against cancers generally. Note substantiation of utility and its scope is required when utility is "speculative", "sufficiently unusual" or not provided. See Ex parte Jovanovics, 211 USPQ 907, 909; In re Langer 183 USPQ 288. Also note Hoffman v. Klaus 9 USPQ 2d 1657 and Ex parte Powers 220 USPQ 925 regarding type of testing needed to support in vivo uses.

Next, applicant's attention is drawn to the Revised Interim Utility and Written Description Guidelines, at 66 FR 1092-1099, 2001 wherein it is emphasized that 'a claimed invention must have a specific and substantial utility'. The disclosure in the instant case is not sufficient to enable the instantly claimed method treating solely based on the inhibitory activity disclosed for the compounds. The state of the art is indicative of the requirement for undue experimentation. See Gressner et al. Front. Biosci. 7: 793-807 2002 (PubMed Abstract provided), Bachman et al., Curr. Opin.

Oncol. 17(1):49-54, 2005, Rosmary J. Akhurst, UCSF Comprehensive Cancer Center, Research Summary pages 1-3, 2007, Kirkbride et al., Expert Opin. Biol. Ther. 3(2), 251-261, 2003, Lahn et al., Expert Opin. Investig. Drugs, 14(6), 629-641, 2005.

Gressner et al., lends support for treating cirrhosis of the liver. Note the reference does not teach treating any or all fibroproliferative disorders or cancer.

Akhurst cited above now teaches the current state of the art in the Research Summary, which clearly contradicts applicants' assertion that all fibroprolifertive disorders and cancers can be treated with TGF. Note Akhurst states, " Despite these developments, the exact mechanism of action of these drugs is not known (e.g. predominant cellular target for each tumor type, systemic or localized effects etc.). TGFβ action is highly context dependent(2), and thus expected outcome in terms of tumor responses and potential side-effects will be difficult to predict.". Akhurst also says, "we are also addressing the role that TGFβ plays in elevated risk of skin tumorigenesis observed in organ transplant recipients..."

Thus, Akhurst is clearly teaching unpredictability of TGFβ treatment.

Bachman et al., also clearly teaches that TGFβ has dual nature. That is it can function as tumor suppressor as well as tumor promoter. Given this fact, one trained in the art has to extensive experimentation with the huge genus of instant compounds and various fibroproliferative disorders and cancers. See entire Abstract.

Note Lahn et al., cited above also states, " TGF-β was quickly recognized as having dual and opposing functions for inhibiting and promoting tumour growth (6).". The concluding paragraph again clearly states additional need for experimentation.

Kirkbride et al., also states, " Current approaches are limited by their nonspecific effects on the TGF-β signaling pathway as TGF-β pathways which specifically mediate immunosuppresion have not yet been defined.".

Taken together, these references clearly teach requirement for further experimentation.

In evaluating the enablement question, several factors are to be considered. Note *In re Wands*, 8 USPQ2d 1400 and *Ex parte Forman*, 230 USPQ 546. The factors include: 1) The nature of the invention, 2) the state of the prior art, 3) the predictability or lack thereof in the art, 4) the amount of direction or guidance present, 5) the presence or absence of working examples, 6) the breadth of the claims, and 7) the quantity of experimentation needed.

1) The nature of the invention: Therapeutic use of the compounds in treating fibroproliferative disorders and cancers that require TGF-β inhibitory activity.

2) The state of the prior art: Recent publications expressed that the TGF-β inhibition effects are unpredictable and are still exploratory. See Gressner et al., Bachman et al., Rosmary J. Akhurst, Kirkbride et al., and Lahn et al., cited above.

3) The predictability or lack thereof in the art: Applicants have not provided any competent evidence or disclosed tests that are highly predictive for the pharmaceutical use for treating any or all condition of the instant compounds. Pharmacological activity in general is a very unpredictable area. Note that in cases involving physiological activity such as the instant case, "the scope of enablement obviously varies inversely

with the degree of unpredictability of the factors involved". See *In re Fisher*, 427 F.2d 833, 839, 166 USPQ 18, 24 (CCPA 1970).

4) The amount of direction or guidance present and 5) the presence or absence of working examples: Specification has no working examples to show treating any or all condition and the state of the art is that the effects of TGF-β inhibitors are unpredictable.

6) The breadth of the claims: The instant claims embrace any or all fibroproliferative diseases and cancers.

7) The quantity of experimentation needed would be an undue burden to one skilled in the pharmaceutical arts since there is inadequate guidance given to the skilled artisan, regarding the pharmaceutical use, for the reasons stated above.

Thus, factors such as "sufficient working examples", "the level of skill in the art" and "predictability", etc. have been demonstrated to be sufficiently lacking in the instant case for the instant method claims. In view of the breadth of the claims, the chemical nature of the invention, the unpredictability of enzyme-inhibitor interactions in general, and the lack of working examples regarding the activity of the claimed compounds towards treating the variety of diseases of the instant claims, one having ordinary skill in the art would have to undergo an undue amount of experimentation to use the instantly claimed invention commensurate in scope with the claims.

MPEP §2164.01(a) states, "A conclusion of lack of enablement means that, based on the evidence regarding each of the above factors, the specification, at the time the application was 'filed, would not have taught one skilled in the art how to make and/or use the full scope of the claimed invention without undue experimentation. In re

Wright, 999 F.2d 1557,1562, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993)." That conclusion is clearly justified here and undue experimentation will be required to practice Applicants' invention.

This rejection is same as made in the previous office action but now limited claim 20 and fibroproliferative disorders and cancers. Applicants' traversal to overcome this rejection is not persuasive.

First of all, instant claim 20 is based on a mode of action to treat any or all fibroproliferative disorders and cancers. Instant claim 20, as recited, is a reach through claim. A reach through claim is a claim drawn to a mechanistic, receptor binding or enzymatic functionality in general format and thereby reach through a scope of invention for which they lack adequate written description and enabling disclosure in the specification.

In the instant case, based on the inhibition of TGF-β by the instant compounds, instant claims reaches through inhibiting and treating any or all diseases in general and thereby they lack adequate written description and enabling disclosure in the specification.

More specifically, in the instant case, based on the mode of action of instant compounds as inhibitor of TGF-β, based on limited assay, it is claimed that treating any or all fibroproliferative disorders and cancers in general, which there is no enabling disclosure.

Secondly, applicants have not provided any pertinent reference to support that any or all fibroproliferative disorders and cancers can be treated based on the instant

mode of action.

The references cited as Exhibit 1-4 do not lend support for treating any or all fibroproliferative disorders and cancers.

For example, by citing US 5,824,655 as Exhibit A, applicants urge that all fibrotic diseases and conditions are treatable. This is not persuasive. Applicants should note that each application is examined on its own merits .

As for Exhibit B , applicants should note that a PCT application is published as is and the issue of scope of enablement clearly distinct for US application.

As for Exhibit C, as noted above, Akhurst cited above now teaches the current state of the art in the Research Summary which clearly contradicts applicants assertion that all fibroprolifertive disorders and cancers can be treated with TGF. Note Akhurst states, " Despite these developments, the exact mechanism of action of these drugs is not known (e.g. predominant cellular target for each tumor type, systemic or localized effects etc.). TGFβ action is highly context dependent(2), and thus expected outcome in terms of tumor responses and potential side-effects will be difficult to predict.".

Thus, Akhurst is now teaching unpredictability of TGFβ treatment.

As for Exhibit D, it clearly calls for further experimentation and contrary to applicants' urging does not teach treating all cancers with TGFβ. Note Slawomir states, "Preclinical studies demonstrated significant antitumor activity of agents targeting this molecule as well as synergy with immunostimulating agents and traditional chemotherapeutics. It is difficult to assess objectively which of the multiple effects of TGF-β contributes the most to tumor growth and metastasis. Clearly, agents that block TGF-β production, secretion,

activation and metabolism should be extensively investigated as a new therapeutic modality for all types of solid tumors."

It is clear the Exhibit D calls for further experimentation.

In addition, as noted above, Bachman et al., cited above, clearly teaches that TGFβ has dual nature. That is it can function as tumor suppressor as well as tumor promoter. Given this fact, one trained in the art has to extensive experimentation with the huge genus of instant compounds and various fibroproliferative disorders and cancers.

Note Lahn et al., cited above also states, " TGF-β was quickly recognized as having dual and opposing functions for inhibiting and promoting tumour growth (6).". The concluding paragraph again clearly states additional need for experimentation.

Kirkbride et al., also states, " Current approaches are limited by their nonspecific effects on the TGF-β signaling pathway as TGF-β pathways which specifically mediate immunosuppresion have not yet been defined.".

Taken together based on these references, contrary to applicants' urging one trained in the art had to extensively undue experimentation to evaluate which disease is treatable without any guidance from instant specification.

Hence, this rejection is proper and is maintained.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and

> the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1 and 4-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cai et al., WO 02/47690 .

Cai et al. teaches several pyrimidine compounds, which include compounds, composition and the method of use claimed in the instant claims. See formula I on page 10 and note when A=C, given the same pyrimidine core, all variable groups overlap with those of the instant claims. Especially see formula II and III on page 11-12

which shows the desired pyrimidine compounds. See entire document for the details of the invention.

See pages 13-34 for various species of pyrimidine compounds. Particularly, see page 22, species 13, 14, page 34, species 1, 2 for pyridylamino bearing pyrimidine species, page 23 species 1,2, page 29, species 10, page 31, species 11 for indoylamino bearing species, and see page 22, species 15, 16 17 for pyrimidinylamino bearing pyrimidine species. For benzimidazoylamino bearing species see page 33, species 16. Note all these differ from instant claims in not having a phenyl or substituted phenyl in 2-posiiton of the pyrimidine ring. However, note in page 13 species 7, 8, page 14, species 18, 19, page 16 species 9, 11, 13, 15 and 17 , Cai et al., teaches phenyl substituents in 2-position. See pages 139-152 for Table of compounds. Especially see compound 73, 75, 81, 46 and 20.

Cai et al differ from instant claims in not exemplifying 2-phenyl substituted pyridiylamino, pyrimidinylamino, indoylamino and benzimidazoylamino pyrimidines, which fall in the genus of instant compounds.

However, Cai et al. teaches the equivalency of alternate choices for the groups in 2-position, 4-position and 6-position those compounds exemplified with specific substituents in pages 13-34 and in Table of pages 139-152 with those compounds generically recited on page 10-12 for Formula I-III See formula I-III and note the definition of various variable groups include several compounds.

Thus, it would have been obvious to one having ordinary skill in the art at the time of the invention was made to make pyrimidine compounds variously substituted

with Ar_1, Ar_2, R_1, R_2 and R_3 as permitted by the reference and expect resulting compounds (instant compounds) to possess the uses taught by the art in view of the equivalency teaching outline above. More specifically, based on the species pointed out above in pages 22, 23, 29 and 31, differ only in not having a phenyl or substituted phenyl in 2-position of the pyrimidine ring and based on the teaching of phenyl substituents in 2-position in species pointed out in pages 13, 14 and 16, one trained in the art would be motivated to make compounds with 2-phenyl substituents along with 4-pyridyl amino, 4-indoylamino, 4-pyrimidinylamino and 4-benzimidazoylamino groups in the pyrimidine ring and expect these compounds to have the same use recited therein.

This rejection is same as made in the previous office action but now includes further explanation of the basis for the rejection. As shown above, the species pointed out differ in one variable only. That is, there is guidance in the reference to make compounds which will differ from the instant compound of formula I in only one variable group at 2-position of the pyrimidine ring. Whereas the species pointed out have pyridyl group at 2-position, instant claims require a phenyl in that position. Again, as pointed out reference clearly permits phenyl in position of the pyrimidine ring. Hence, contrary to applicants' urging , it would be obvious to one trained in the art that 2-phenyl substituted pyrimidines bearing pyridylamino, indoylamino, pyrimidinylamino and benzimidazoyl amino groups at the 4-position would be also have the same use taught in the reference.

As for the issue of "equivalency" the term is used in the sense alternate choices are equivalent as far as the desired activity of the genus of compounds. In other words,

as much as alternate choices embraced as substituents in the pyrimidine core are assumed to have the same activity, the alternate choices setforth in the reference are given the same meaning. More specifically, instant claims embrace various variables as alternate choices of substituents in the pyrimidine and as recited in claims 20 and 23 are said to have the same utility. Likewise, alternate substituents taught in the reference for the pyrimidine core would also result in compounds with the use taught in the reference. Hence, one trained the art would be motivated make compounds with alternate choices substituents with the guidance provided in the reference and expect these compounds have the same use taught foe exemplified compounds of the reference.

Hence, this rejection is proper and is maintained.

Claims 1, 4-19 and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kleemann et al., US 5,849,758.

Kleemann et al. teaches several pyrimidine compounds, which include compounds claimed in the instant claims. See formula I on column 1 and note when Z is N, given the same pyrimidine core, and A is aryl or heteroaryl, compounds taught by Kleemann et al include those of the instant claims. See column 1-3 for the details of the invention. See column 3-5 for various species of pyrimidine compounds. See Table X for various compounds, which include instant compounds.

Kleemann et al, although exemplifying several compounds, which fall in the genus of instant compounds, does not fully exemplify all compounds embraced in the genus of Formula I. However, Kleemann et al. teaches the equivalency of those

compounds exemplified with specific substituents with that generically recited for formula I. See formula I and note the definition of various variable groups include several compounds. Thus, it would have been obvious to one having ordinary skill in the art at the time of the invention was made to make variously substituted pyrimidine compounds as permitted by the reference and expect resulting compounds (instant compounds) to possess the uses taught by the art in view of the equivalency teaching outline above.

This rejection is also same as made in the previous office action but now limited currently pending claims. Applicants' argument to overcome this rejection is not persuasive.

Applicants argued that alternate choices are not equivalent. That is according applicants, although Kleeman et al., teaches compounds of formula I wherein X=O, which anticipated instant compounds and was obviated by excluding X=O, teaching of Kleeman et al., would only limited to exemplified compounds not other alternate choices. This is not persuasive.

First of all, Kleeman permits X=O and X=S as much as applicants are permitting X=NR and X=S in currently pending claims . It should be pointed out the original claims had X=O as well. Therefore alternate choices should be given equal weight whether it is instant application or a reference.

Secondly, applicants argued that since X=S compounds are not exemplified and Kleeman et al., gets good results with X=O compounds, the reference is limited X=O teaching only. This is again not persuasive. There is no explicit teaching or statement in

Kleeman e t al., to indicate the X=S compounds are inactive. Applicants have not provide d any such evidence.

Thirdly, applicants have not made any compound of instant claims wherein X=S but relies on compounds wherein X=O to assert activity.

Finally, as for legal standard, note In re Bruckel which states " References must be considered under 35 U.S.C 103, not only for what it expressly teaches but also for what it fairly suggests; all disclosures of prior art, including unpreferred embodiments must be considered in determining obviousness". In re Bruckel, 201 USPQ 67.

The equivalency teaching of alternate choices of X =O with X= S, should therefore be given due consideration as much as instant Markush choices of X mentioned above.

This rejection is proper and is maintained.

Conclusion

Any inquiry concerning this communication from the examiner should be addressed to Venkataraman Balasubramanian (Bala) whose telephone number is (571) 272-0662. The examiner can normally be reached on Monday through Thursday from 8.00 AM to 6.00 PM. The Supervisory Patent Examiner (SPE) of the art unit 1624 is James O. Wilson, whose telephone number is 571-272-0661. The fax phone number for the organization where this application or proceeding is assigned (571) 273-8300. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAG. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-2 17-9197 (toll-free).

Venkataraman Balasubramanian

3/19/2007